



BREAST CANCER SURVEILLANCE CONSORTIUM MANUSCRIPT AND GRANT PROPOSAL FORM

ADMINISTRATIVE

1. General information about the proposal

Date proposal submitted to the BCSC	
Project title:	
Short title (5 words or less):	
Is this project associated with a previously approved BCSC concept, grant or manuscript proposal?	<input type="checkbox"/> No <input type="checkbox"/> Yes: please provide tracking number: _____
Project leader name:	
Affiliation/ organization:	
Address:	
E-mail address:	
Phone number:	

2. List all collaborators associated with this proposal (add rows if more than 8):

Name	Affiliation	Email Address	Will s/he be part of the small working group? ** YES/NO/N/A

****Only applicable** for a manuscript that arises from the use of pooled BCSC data from one or more consortium sites that use the SCC to conduct analyses (or the lead investigator is a member of the BCSC).

3. Proposed Timetable:

Date of proposed initiation: _____

Proposed completion dates: _____

Anticipated deadlines (if applicable): _____

4. Purpose of this request (Double-click the checkbox that best applies. A separate proposal form should be filled out if data is needed for multiple purposes (e.g., a grant and a manuscript).)

- Data analysis for manuscript Target journal: _____
- Grant application for a project that will involve BCSC data (Note: Once the grant is funded, a separate proposal form is required for each resulting manuscript using BCSC data)
- Inputs/calibration data for simulation, decision analysis, or cost-effectiveness model
- Development of statistical methods for publication: Target journal: _____
- Development of statistical methods – Other: Please specify: _____
- Other: Please describe: _____

5. Which registries will be included in this study? (Double-click boxes to mark all that apply):

- Colorado (data through 2006 only) San Francisco
- New Hampshire Vermont
- North Carolina Group Health (Western Washington)
- New Mexico Chicago (for BCSC-P01 studies only)

6. Would you prefer an analyst from the SCC do the analysis? (Double-click appropriate box):

- YES** (please skip to question #8)
- NO, I would like a dataset sent to me, but will perform the analysis** in collaboration with the Statistical Coordinating Center
Please explain how you will store and protect BCSC data from unauthorized access:

Please list the members of your project who will have access to the data:

- NO, I would like a dataset sent to me with minimal consultation** with the Statistical Coordinating Center
Please explain how you will store and protect BCSC data from unauthorized access:

Please list the members of your project who will have access to the data:

Other (please describe):

7. If you would like a dataset sent to you, please indicate the type of data request. *Any data request that includes dates, zip codes, or specific ages >89 years will require completion of a HIPAA data use agreement after approval of your proposal. The SCC can't release masked BCSC site identifiers or facility-level information. Analyses that require these variables must be done by the SCC.*

De-identified data/ **aggregate** data

De-identified **individual level** data (without dates, zip codes, specific ages >89 or BCSC site IDs)

Limited dataset: De-identified individual level data with: **(mark all that apply):**

Dates

Specific age >89 years

Zip codes (*will generally not be released without careful consideration & protection in place*)

Other (please describe) _____

8. Supplemental funding

Does this study involve grant or other supplemental funding?

NO

YES, we have funding from _____ **Start & end dates** (mo/yr – mo/yr) _____

_____ **Start & end dates** (mo/yr – mo/yr) _____

YES, we plan to apply for a grant from _____ (due date _____)

Does this study involve the support or collaboration of a for-profit entity?

NO

YES, we have support from and/or are collaborating with _____

Do you intend to use the data to patent any process, aspect, or outcome of the analysis?

NO

YES

RESEARCH OBJECTIVES & METHODS:

9. Please fill out the content areas of your proposed research below. Proposal length should preferably be no more than 3 pages, excluding mock tables, and should not exceed 10 pages.

Specific Aims

Brief Background (one or two paragraphs)

Study Years

Inclusion/exclusion criteria

Outcome variable(s)

Main exposure variables(s)

Other covariates/possible confounders

Statistical Approach

Power analyses, if applicable

Mock Tables

10. Key words (Double-click boxes to mark all that apply):

- | | |
|--|---|
| <input type="checkbox"/> Breast biopsy | <input type="checkbox"/> Health services research |
| <input type="checkbox"/> Breast MRI | <input type="checkbox"/> Hormones |
| <input type="checkbox"/> Breast ultrasound | <input type="checkbox"/> Imaging facilities |
| <input type="checkbox"/> Breast density | <input type="checkbox"/> Imaging performance |
| <input type="checkbox"/> Comparative effectiveness | <input type="checkbox"/> Radiologists |
| <input type="checkbox"/> Cost Analysis | <input type="checkbox"/> Risk factors |
| <input type="checkbox"/> Digital mammography | <input type="checkbox"/> Risk modeling |
| <input type="checkbox"/> Diagnostic mammography | <input type="checkbox"/> Screening mammography |
| <input type="checkbox"/> Disparities | <input type="checkbox"/> Statistical methods |
| <input type="checkbox"/> Film mammography | <input type="checkbox"/> Treatment |
| <input type="checkbox"/> Geographic access | <input type="checkbox"/> Other: |

11. Are you requesting data only from the BCSC Research Resource (exams and events through 2009)? (Double-click boxes to mark all that apply):

- Yes**
- No**

If you checked "YES" then you are done with this form.

The following questions **ONLY** apply if this project uses data (or is related to the aims of) BCSC research projects, such as:

- “Risk-based breast cancer screening in community settings” (BCSC-P01)
- “Effectiveness of pre-operative breast MRI in breast cancer surgery and outcomes” (EMPRESS)
- “Surveillance imaging modalities for breast cancer assessment” (SIMBA)

If you are not sure whether your grant fits this definition, please contact the SCC facilitator who is helping you with this proposal form.

1. Which Project/Core is proposal affiliated with? (Double-click boxes to mark all that apply and indicate which is primary. If this proposal uses data collected under the P01 but isn't related to the P01 project or CE Core aims please check “Core B”.)

- | | |
|---------------------------------------|-----------------------------------|
| <input type="checkbox"/> Project 1 | Primary? <input type="checkbox"/> |
| <input type="checkbox"/> Project 2 | Primary? <input type="checkbox"/> |
| <input type="checkbox"/> Project 3 | Primary? <input type="checkbox"/> |
| <input type="checkbox"/> Core B | Primary? <input type="checkbox"/> |
| <input type="checkbox"/> Core C | Primary? <input type="checkbox"/> |
| <input type="checkbox"/> Other: _____ | Primary? <input type="checkbox"/> |

2. Data sets (Double-click boxes to mark all that apply)

- BCSC Research Resource (archived BCSC data – exams and events from 2009 or earlier)
- BCSC-P01 data (exams and events occurring 2010 and later; includes MRI, advanced imaging data)
- AIM data (e.g., test set data)
- FAVOR data (radiologist survey)
- P01 Project 1 data (SNPs, hormones, volumetric breast density)
- P01 Project 3 data (geocoded census data, travel time data)
- BCSC Medicare data, original linkage (years 1998-2006)
- BCSC Medicare data, new linkage (years 2005-2010)
 - Related to EMPRESS aims?
 - Related to P01 aims?
- Other: Specify _____

Administrative Items that will be completed by the Statistical Coordinating Center:**Assigned Project Number?** (Same as above, if number previously assigned) _____**Date of Steering Committee Review:** _____**Steering Committee Action:**

- Approved
 Not Approved
 Conditionally Approved (state reason): _____

Is this proposal a:

- Grant – Title: _____
 Manuscript
 Other – Describe: _____

Is this proposal a data request (Defined as a data request if answer to #6 is NO)

- YES
 NO

Is the lead investigator from:

- The BCSC-P01 The SCC Contract
 On the Steering Committee
 Not on Steering Committee
- External to BCSC with SCC involvement (Name of BCSC Facilitator _____)
 External to BCSC without SCC involvement (Name of BCSC Facilitator _____)
 Ancillary grant:
 What is the name of this grant? (e.g., EMPRESS, SIMBA, CISNET) _____
 What is the name of BCSC Facilitator _____

Is this grant using BCSC data?

- YES
 NO

What is the current status of the project:

- In Analysis
 In Queue
 Completed
 Track for grant funding

SCC analyst needed?

- YES (who?) _____ Should s/he be added to the author list? _____
 NO

SCC Programmer needed?

- YES (who?) _____
 NO

Type of data requested:

- N/A – data not requested – no analysis needed at this time (e.g., grant proposal)
 N/A – data not requested – SCC will do the analysis OR is a site-specific analysis
 Aggregated de-identified data
 Data contains reader, site, and/or facility IDs
 De-identified individual level data (w/o identifiers – e.g., no zip codes, ages >89 or site identifiers)
 De-identified individual level data with dates, specific age >89, or zip codes

Complexity of the project

- Simple
- Average
- Complex

If data was requested, has a call been made delineating points in the Synopsis document?

- YES
- NO
- N/A